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Award Number: W81XWH-04-2-0015

TITLE: Continuous Pre-Hospital Data as a Predictor of Outcome Following Major Trauma: A Study Using Improved and Expanded Data

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REPORT DATE: June 2005

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
01-06-2005	Annual	23 Jan 2004 - 22 May 2005

4. TITLE AND SUBTITLE
Continuous Pre-Hospital Data as a Predictor of Outcome Following Major Trauma: A Study Using Improved and Expanded Data

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-04-2-0015

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Southwest Research Institute
San Antonio, TX 78238

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Abstract follows.

15. SUBJECT TERMS
Noninvasive, trauma, outcome, pre-hospital, EMS, predict, wireless, telemedicine

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
U	U	U	UU	13	

ABSTRACT

This study is designed to acquire near continuous physiologic measurements, beginning at the earliest practical time after injury, on large numbers of injured patients with severe trauma. The study will utilize commercially available FDA-certified monitoring equipment operating in a fleet of front-line ground EMS units currently serving a large metropolitan area with a major trauma center, and operating within an existing mobile wireless telemedicine network. First Responders represent the earliest opportunity to acquire meaningful medical data in injury cases. This data will be correlated with significant clinical outcomes within the first 24 hours of admission at a trauma center and entered into a research database. Analysis of this database may allow development of models that predict outcome and the need for life-saving procedures. During the reporting period, a foundation has been laid to implement the data collection operations. A "proof-of-concept" process for manually collecting, processing, and depositing pre-hospital physiological data for trauma patients has been defined. Research protocols have been developed and all required IRB approvals have been obtained. The implementation of physical and electronic data collection facilities for this project, and to pave the way for future automation of data collection/upload, is well under way.

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Introduction

The subject project is intended to implement and test a "proof-of-concept" capability to collect relevant physiological and treatment data for seriously injured trauma patients in support of the U.S. Army's "Advanced Capabilities for Combat Medics" program. The information that is sought includes pre-hospital physiological data for qualifying patients as well as post-arrival and outcome data. This project represents the first known attempt to accomplish these tasks within a system of ground ambulances responding to incidents and caring for and transporting patients to Level 1 Trauma Centers. Ground Emergency Medical Services (EMS) represents the earliest practical opportunity, for most civilian traumatic injury cases, to begin to acquire the data that is needed. This project builds on the existing LifeLink mobile telemedicine network in San Antonio to accomplish these goals. The scope of the subject project is to establish "proof-of-concept" data collection capabilities in five EMS units operating within the LifeLink network and one receiving hospital, to establish required research protocols and approvals to facilitate the data collection and research operations, to operate the data collection system for one month, and to examine the resulting data and draw preliminary conclusions about the capabilities and potential benefits of initiating pre-hospital data collection early in qualifying trauma injury cases.

Body

This section of the report presents discussion and significant accomplishments/problems encountered in the conduct of the subject project for the reporting period. The section is organized to present this information as associated with relevant tasks and subtasks of the approved Statement of Work for the project.

TASK 1. To implement the EMS ambulance fleet for data collection and obtain Institutional Review Board (IRB) approvals for data collection protocols.

Subtask 1.a Investigate monitor configuration and data collection process.

The target population for data collection in this project is adult trauma patients being transported Code 3 to Brooke Army Medical Center (BAMC) by the San Antonio Fire Department, Emergency Medical Services (SAFD/EMS) division, in ambulances equipped with suitable monitors and operating within the LifeLink project. In order to acquire and use the electronic physiological data collected on these patients, it is necessary to understand the monitor configuration (setup) that will be used by paramedics in normal patient care practice in the field. It is also necessary to understand and define monitor configuration parameters and process issues to assure that the desired data can be captured, stored, and communicated/retrieved for use in the project.

Southwest Research Institute® (SwRI®) has negotiated and concluded agreements with Medtronic Emergency Response Systems, Inc. (Medtronic) who is the manufacturer of the LifePak 12 physiological monitor used by SAFD/EMS. Additional agreements with the

University of Texas Health Science Center San Antonio (UTHSCSA), which provides medical direction for SAFD/EMS, and the U.S. Army Institute of Surgical Research (USAISR), which manages the Advanced Capabilities for Combat Medics program, have been negotiated and concluded for the subject project. Part of the USAISR program is commonly called the Trauma Vitals project which needs patient data such as that to be provided by the subject SwRI project.

Pre-hospital physiological data collection for this project is to be based on current approved SAFD/EMS protocols for patient care and monitoring during the pre-hospital interval of patient care and transport. SwRI investigated and documented the established protocols for EMS monitoring for the subject population for this study. Three reference patient data files were acquired for engineering purposes using volunteer paramedics as subjects. The three reference files have been used in developing and testing the pre-hospital data acquisition and upload process.

The monitor configuration used by SAFD/EMS for the target population for this study includes 5-lead Electrocardiogram (EKG), Heart Rate (HR), Non-Invasive Blood Pressure (NIBP), Oxygen Saturation (SPO_2), and other data. The monitor is capable of acquiring and storing a single (waveform) channel of EKG data continuously and acquiring/storing all active EKG (waveform) channels for short periods after being triggered by a manual command. Additional discrete numerical physiological data such as NIBP and event data as detected by the monitor are also acquired and stored within the monitor for eventual retrieval.

The pre-hospital data collection process for this project must be "transparent" to the patient care and transport mission of EMS. This "rule" has guided the development of the process planned for the subject study. The data collection process to be used during the subject study is viewed as a "proof-of-concept" process which is somewhat of a "manual" process that is expected to yield usable data. The subject "proof-of-concept" data acquisition process development includes development and use of technical processes and building blocks that are extendable to future more automatic and efficient data acquisition methodologies.

During a typical EMS "run" for adult cases, the physiological monitor is applied to the patient and an EKG strip and discrete numerical parameter values are acquired and documented in the EMS run sheet. If vital signs are unstable or worrisome to the paramedic, the patient will be monitored for a longer period during the transport, and additional EKG strips and data will be acquired and included in the run sheet. For potentially qualifying patients for the subject study, paramedics will attempt to acquire monitor data during the entire pre-hospital care interval by leaving the monitor attached and running till the unit reaches a receiving hospital. The LifePak 12 monitors to be used in this project have been configured such that when the monitor is turned off after a monitoring session, waveforms and data acquired during the monitoring session are automatically stored in a patient data archive file within the monitor. The archived data files stored in the monitor are encrypted in a proprietary data format and further work is required in order to access the raw data.

The SAFD/EMS organization will identify qualifying patient transports for the subject project and alert SwRI. SwRI and SAFD/EMS will arrange access to the EMS unit and the relevant monitor for the purpose of retrieval of the archived file.

Patient data files acquired and stored in the LifePak 12 monitor are encrypted in a proprietary format. Medtronic produces and sells software that is designed to retrieve and process patient data for post-run reporting and review; however, this software is also proprietary and conducts operations on the data file (changes file types and formats, etc.) at each stage of processing, including retrieval from the monitor. For this reason, SwRI has researched and tested independent computer communications standards that can be used for retrieval of desired archived data from the LifePak 12 monitor without changing or corrupting the file or included data. SwRI has implemented communications software that is script-driven and can be "called" from other software applications and successfully retrieves stored files from the LifePak 12. This provides the opportunity for future refinement and automation in the data acquisition process, including wireless data file transfers using the LifeLink network.

Using the independent data communications standard technique, SwRI will recover qualifying archived patient data from the monitor used in a qualifying EMS run and will store the un-corrupted, but proprietary, data files on a laptop computer. As a quality control measure, SwRI has acquired and tested the capability to import copies of recovered data files into Medtronic reporting software for review of the file and data records before leaving the EMS unit. This will enable SwRI to be sure that files of interest have been successfully recovered. Test copies of recovered archived files only will be reviewed at this time as the process will alter the files. At this point, patient data files will only be identifiable by the individual monitor serial number (co-relatable with the individual EMS unit) and the date and time of the event as contained in the file data.

SwRI and Medtronic are currently collaborating to develop a special data extractor utility that will allow SwRI to process retrieved proprietary patient data files to produce data that is usable by the Trauma Vitals database. The initial version of the utility is essentially complete and under review and test using short generic, but known, sample patient data files. The test and review process will be continued to include actual files acquired within SAFD/EMS units using actual monitors that will be used in project data collection.

The output of the data extractor utility is in the form of multiple eXtensible Markup Language (XML) data files. The content and structure of the XML data files conform to evolving data format specifications as coordinated by USAISR to facilitate data transmission between the LifePak 12 data files and the Trauma Vitals database.

When actual patient data collection is initiated for this project, SwRI will process the retrieved LifePak 12 files and associate the files with the qualifying EMS patient run. The processed XML data files will be uploaded to the Trauma Vitals database, and SwRI will coordinate with the appropriate Trauma Vitals project Research Nurse (RN) at BAMC. The RN will have the capability to access the pre-hospital physiological monitor data in the Trauma Vitals database and will begin to populate the database with relevant post-arrival data for each case.

Subtask 1.b Implement data collection configuration in five ambulances.

The San Antonio Fire Department, EMS division, is upgrading the physiological monitors used in its field ambulances to the LifePak 12 monitor manufactured by Medtronic Emergency Response Systems. Not all of the SAFD ambulances have been upgraded to include the LifePak 12 monitors at this time due to municipal budget issues. SAFD ambulances that have not been upgraded to the LifePak 12 monitor use the earlier LifePak 10 monitor. Unlike the LifePak 12, the LifePak 10 does not have the capability to store acquired physiological data or communicate such data to other devices. Both of these functions are needed in order to collect electronic data for this project. There are enough LifePak 12 monitors available in the service at this time to populate the ambulances that will be participating in this project.

The LifePak 12 monitor requires special configuration to enable communication of archived files, etc., to other devices. SwRI coordinated with SAFD/EMS and Medtronic to facilitate configuration of all of the SAFD/EMS LifePak 12 monitors that are in service. This task was accomplished by SwRI and staff from Medtronic at a SAFD/EMS facility in San Antonio.

The original SAFD/EMS LifeLink ambulance fleet is being retired and replaced with new units due to age and wear. SwRI has accomplished the task of coordinating access to the relevant units with SAFD/EMS in order to remove the LifeLink equipment. The equipment recovery task was accomplished by SwRI and the Texas Department of Transportation (TxDOT) at a SAFD facility. Five LifeLink equipment sets are in the process of checkout, refurbishment, test, and other preparations for installation in new SAFD/EMS ambulances by SwRI. SwRI has accomplished approximately 80% of the required preparation and installation of recovered LifeLink equipment for the first of the project ambulances. The remaining four LifeLink equipment sets are located in SwRI labs and are nearing completion of the required preparation and test prior to installation in new SAFD/EMS ambulances.

New SAFD/EMS ambulances are specified to contain special wiring and other accommodations built into the ambulances to accommodate installation and operation of LifeLink equipment. During the installation of refurbished LifeLink equipment in the first unit, however, it was discovered that some of the pre-arranged wiring and accommodations were omitted at the factory. SwRI is developing a work-around for this problem for currently available new SAFD/EMS ambulances and has coordinated correction of the problems with SAFD/EMS and the ambulance manufacturer for future units.

Access by SwRI to SAFD/EMS ambulances for upgrade and test has been limited to date primarily due to two reasons:

1. There has been a delay in negotiating and concluding appropriate agreements between SwRI and SAFD/EMS. The delays are primarily in processing the agreement through the city's legal department which represents SAFD in such matters. The delays have nothing to do with support for the subject project within SAFD; however, SAFD management is grappling with acute general budget and organized labor issues in an environment of strained municipal government operations during recent times. There has been, however, steady communication and slow progress. A jointly-crafted draft Memorandum of Understanding (MOU) agreement is

currently under review by the city's legal department and meetings/discussions to conclude the agreements are anticipated in the near future.

2. There is a desire to install the LifeLink equipment in new or nearly new ambulances in order to achieve the longest "life" of the operational units in the fleet. This involves considerable coordination between SwRI and SAFD/EMS to select units and wait for their availability or delivery.

Subtask 1.c Specify adaptations required for database.

USAISR has worked with SwRI, SAFD/EMS, and UTHSCSA, to develop and implement a set of data file specifications for LifePak 12 data files that are to be uploaded into the Trauma Vitals Database. The development of the LifePak 12 data extractor utility by SwRI and Medtronic has been subject to the development of XML data file specifications for the Trauma Vitals program. Output files produced by the special project LifePak 12 data extractor utilities are under review and test at the time of this report.

Subtask 1.d Develop and submit protocols for three IRB approvals [local, one hospital, and the Human Subjects Research Review Board (HSRRB)].

SwRI and USAISR have collaborated on development and approval of the protocols for research and data collection involving human subjects for the subject project. The protocols have been developed by amending the existing protocol originally approved by the BAMC IRB for pre-hospital data collection at USAISR (actually a number of incremental amendments). The amended protocol was first submitted and approved by the IRB at BAMC and then at the Multi-Assurance IRB at UTHSCSA. The UTHSCSA IRB is the IRB with oversight for SwRI, University Hospital, and others in San Antonio area. Finally, the subject protocols were submitted and approved by the HSRRB at Ft. Detrick.

The title of the protocol is "Capture and Analysis of Prehospital Trauma Vital Signs for Enhanced Remote Triage and Prediction of Life Saving Interventions." The approved protocol is identified with HSRRB Log No. A-12859.b, and notice of the approval of continuing review and amendment of the protocol by HSRRB was received in February, 2005.

The research protocol amendments essentially added additional study sites (including SwRI, SAFD/EMS, and BAMC) and additional Associate Investigators and other criteria required to enable the data collection and data handling/processing planned for the subject project.

Uncertainty in the timing and responsibility for development and IRB approval for the research protocol for the subject project was a major problem for the project team. Project planning was based on USAISR taking full responsibility for these tasks; however, by the time that the project was actually initiated, the budget and staff availability environment had changed significantly at both SwRI and USAISR. Under the project plan, the conduct of these tasks was not funded by the project as USAISR operates under its own budget, and the ability to absorb these

responsibilities into the project goals/funding was very limited. This issue was overcome by collaborative effort between USAISR and SwRI (with USAISR taking the lead) and included achieving the required documentation and approvals by amending a previously approved protocol rather than developing a new protocol.

Subtask 1.e Semi-Annual Report.

Quarterly reports (or substituted participation in Programmatic Line Reviews) have been submitted for the subject project. A semi-annual report would be redundant and is not included in the reporting requirements for the subject project.

TASK 2. To implement adaptations for the existing Trauma Vitals Database for San Antonio data and set up the data collection organization.

Subtask 2.a Implement data collection facilities at one hospital

Work on this subtask is due to initiate in the near future.

Subtask 2.b Implement database adaptations.

The Trauma Vitals database has been modified to process physiological data uploads using specified XML data files for the LifePak 12 monitors used by SAFD/EMS for pre-hospital physiological data collection. The database system has been modified to provide data import and exchange between multiple data collection centers. These modifications will allow data collected through the SwRI project to be imported and shared on the system using the same formats currently supported by other data collection sites.

Work is still ongoing to provide a native interface for the XML numeric and waveform data formats identified for the project. This part of the system will be implemented as part of a new server side architecture currently being developed by USAISR to replace the current Java-based system. The new Hypertext Preprocessor (PHP)-based system is being designed to allow for better data management and processing as new data collection sites are added to the Trauma Vitals project. Moving data processing and database access functionality to the server will provide performance increases for data sites which have limited data connection capabilities.

Subtask 2.c Implement data collection system and familiarize EMS and hospital personnel with project procedures

Work on this subtask is due to initiate in the near future.

Subtask 2.d Annual Report.

This report is an annual report.

TASK 3. To conduct operations to collect data.

Subtask 3.a Collect hospital and pre-hospital data derived from existing practices for Code 3 trauma patients transported to one hospital by SAFD LifeLink ambulances for one month.

Work on this subtask is due to initiate upon completion of Task 2.

Subtask 3.b React to problems in facilities and organizations.

Work on this subtask is due to initiate coincident with Task 3.a.

Subtask 3.c Review and analyze data and refine procedures.

Work on this subtask is due to initiate coincident with Task 3.a

Subtask 3.d Final Report.

Work on this subtask is due to initiate after Task 3.a is under way.

Key Research Accomplishments

1. A "proof-of-concept" ground EMS pre-hospital data collection process has been defined and is the basis of the balance of work in the project.
2. The research protocol for project data collection and research has been developed and submitted. Local IRB and HSRRB approvals have been obtained.
3. An independent raw-data recovery process and tool for the LifePak 12 physiological monitor has been developed and tested.
4. The initial version of a physiological data-extraction utility is nearing completion. Sample files have been acquired from volunteers in an EMS unit, and sample extracted data files for upload to the Trauma Vitals database are under review.
5. The LifeLink ambulance refurbish and renewal process and accommodations are designed and materials are in place. The LifeLink equipment has been recovered from old units. The first EMS unit renewal is 80% complete. The remaining LifeLink equipment sets are nearing completion of refurbishment and test.
6. LifePak 12 monitors in the LifeLink EMS fleet have been configured to accommodate data storage and extraction.

7. Agreements for the subject project are in place between SwRI and USAISR, UTHSCSA, and Medtronic.

Reportable Outcomes

1. SwRI has developed a new initiative to support and expand the data collection and research operations that are part of the Trauma Vitals program. The Parameter-based Remote Objective Pre-Hospital Emergency Triage (PROPHET) program has achieved first-year funding support by U.S. Congressional action, and future support is anticipated.

2. The subject project, the Trauma Vitals project, and the PROPHET initiative were displayed and showcased during the 2004 Annual Meeting and Convention of the Intelligent Transportation Society of America (ITSA). During this major convention in San Antonio, a live exercise was conducted by municipal public safety agencies. The drill exercise was a simulated "suicide bomber" attack inside a convention hall with multiple casualties. A LifeLink-equipped ambulance along with remote diagnostic ultrasound (linked to BAMC) and Trauma Vitals demonstrations and displays were integral parts of the exercise. The exercise was a well-advertised and well-attended feature of the ITSA convention. Approximately 30 volunteer victims with moulage were assessed and evacuated during the exercise. The ITSA organization maintains a major emphasis on the interaction of transportation systems and emergency response issues and future potential collaborations are currently being explored.

3. SwRI hired new staff to support the PROPHET initiative and the USAISR Trauma Vitals project. It is anticipated that SwRI will facilitate continued support for the Trauma Vitals project in the near term through an Interagency Personnel Agreement with USAISR.

Conclusions

Significant amounts of high quality, but difficult to acquire, data is needed for the Trauma Vitals project. The nature of the research program suggests that obtaining data during as much of the evolving physiological presentation for trauma patients is advantageous and especially that collection of data and trending beginning as soon after an injury occurs as can be accomplished may yield particularly relevant and usable information.

Perhaps the earliest practical opportunity to begin collection of pre-hospital data is to position First Responders in a community to help accomplish the task. Another meaningful opportunity to obtain such data is to acquire data in air evacuation helicopters; however, these aircraft almost always arrive on a scene much later that First Responders.

The opportunity to collect data using a fleet of operating EMS units operating in a large municipality and that routinely transport trauma patients to both military and civilian trauma centers exists in the subject project. Further, the existence of a widely distributed mobile broadband digital communications link between ambulances in the field and the trauma centers

(the LifeLink project) can facilitate more transparent and easily managed data collection in the emergency patient pre-hospital care environment.

During the reporting period for the subject project, the foundation has been laid to implement the data collection operations as described above. A "proof-of-concept" process for "manually" collecting, processing, and depositing pre-hospital physiological data for qualifying trauma patients has been defined. Research protocols involving human subjects for this project have been developed and all required IRB and HSRRB approvals have been obtained. The implementation of physical and electronic accommodations to facilitate the proof-of-concept data collection during this project and pave the way for future practical automation of the data collection and upload process is well under way.

Future plans for this project include completion of the physical and electronic accommodations for the proof-of-concept data collection process and implementation of the data collection structure to operate for one month with five equipped ambulances and qualifying patient cases at BAMC per the approved Statement of Work. The resulting data will be deposited in the Trauma Vitals database and examined. Conclusions will be drawn about the data and the process with respect to the needs of the Trauma Vitals project, and these results and conclusions will be reported.

SwRI has developed an initiative based on the subject initial project to include future automation, expansion, and extension of the data collection and Trauma Vitals research. The PROPHET initiative has been included in the Defense Authorization Bill for FY05, and it is anticipated that this support will be continued and expanded in the foreseeable future. The PROPHET program and its relationship to emergency patient care was showcased during a live emergency drill within a major convention during the reporting period. Future plans for the PROPHET program include refinement, automation, extension, and expansion of the data collection efforts. Additional research components will be added to further analyze collected data to help identify meaningful predictive trends and algorithms and to expand data gathering and research work to include additional potential field triage advances. It is anticipated that this work will ultimately lead to deployable prototype equipment, field and clinical trials, and development/distribution of the technologies to military as well as civilian casualty care organizations.